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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,119	04/16/2004	Toyoko Kusama	NANP119US	1349
7590 09/30/2009 Gregory Turocy Amin & Turocy, LLP 24th Floor, National City Center 1900 East 9th Street Cleveland, OH 44114			EXAMINER CHUNDURU, SURYAPRABHA	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 09/30/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/826,119

**Applicant(s)**

KUSAMA ET AL.

**Examiner**

Suryaprabha Chunduru

**Art Unit**

1637

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,26-34,36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,25 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 10, 2009 has been considered.

***Status of the Application***

2. The action is in response to the RCE filed on August 10, 2009. Currently claims 24-25, 35 are under examination. Claim 1-23, 26-34, 36-37 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed unpersuasive.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-25, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saulle et al. (J Animal Sciences, Vol. 77, pp. 3398-3399, 1999) in view of Lowe et al. (Nucleic Acids Research, Vol. 18, No. 7, page 1757-1761, 1990).

Saulle et al. teach a nucleic acid sequence of ATPase8 mitochondrial gene of claims 24 and 35 that identify a ruminant species, comprising primer sequences of SEQ ID No. 3-6 as claimed (see page 3398, col.1, paragraph 5, Accession number AF104682, and also see sequence alignment from GenEmbl. database).

With regard to claim 25, Saulle et al. teach that said nucleic acid is of a ruminant deer (alpine ibex) (see page 3398, col. 1, paragraph 5). However did not teach the combination of primers or primer pairs.

Lowe et al. teach a method for designing primers and evaluating their performance wherein Lowe et al. disclose a computer program for rapid selection of oligonucleotide primers for polymerase chain reaction (see page 1757, col. 1, abstract). Lowe et al. teach that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted size and also hybridize with the appropriate cDNA or internal oligonucleotide probe (see page 1760, col. 2, paragraph 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the known nucleic acid sequence as taught by Saulle et al. with a step of generate primers and designing primers as taught by Lowe et al. to amplify and increase the primer specificity and to detect a ruminant-specific DNA because the ATPase8

mitochondrial gene sequence is known (as taught by Saulle et al.) to an ordinary skill in the art at the time the invention was made, and it is obvious to generate primers from the known sequences as taught by Lowe et al. The ordinary artisan would have had a reasonable expectation of success that such primers or primer pairs generated using known sequences as taught by Saulle et al. in view of Lowe et al. to amplify a ruminant-specific DNA for detection because the claimed primers are functional equivalents of the sequences taught by Saulle et al. and Lowe et al. explicitly taught that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted size (see page 1760, col. 2, paragraph 1). The ordinary artisan would have been motivated to generate a number of said primers and primer pairs for detection of ruminant-specific DNA, such primers and primer pairs are considered functionally equivalent to the claimed primers and primer pairs. Further, selection of specific oligonucleotides for specific  $T_m$  represents routine optimization with regard to sequence, length and composition of the oligonucleotide, which routine optimization parameters are explicitly recognized in Lowe et al. (This clearly shows that every primer would have a reasonable expectation of success). As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the probe or primer selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

***Response to arguments:***

4. With regard to the rejection of claims 24-25, and 35 under 35 USC 103(a) as being unpatentable over Saulle et al. in view of Lowe et al., Applicants' arguments and the amendment were fully considered and found unpersuasive. Applicants argue that the instant claims as amended recite the property of the primer pair and utility of the primer pair. With regard to the appeal decision, Applicants also argue that the primers are directed toward one specific species and assert that the office did not explain that the combination could predictable generate primers for identifying ruminants but not non-ruminants. Further Applicants argue that mere disclosure of a genus does not anticipate or make prima facie obvious a species and cites MPEP 2144.08 and asserts that the combination of Saulle in view of Lowe et al. only teach utilities of genus of primers and does not discriminate a species and argue that the office did not explain the utilities of genus disclosed by Saulle et al. and assert that known sequence of ATPase8 cannot explain the utility of the primer pair in identifying only ruminants and not non-ruminants and there is no motivation for one skilled in the art to select the claimed primer pair from a larger genus of primers.

Applicants' arguments were found unpersuasive. First, with regard to the claims as amended reciting utility of the primer pair to identify ruminants, Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re*

Otto, 136 USPQ 458, 459 (CCPA 1963). Thus, intended use is not given any patentable weight since the prior art teaches said primers.

Second, with regard to the arguments on the property of the primers as noted in MPEP2111.02 the discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). MPEP 2112 "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Accordingly the property is inherent in said primers.

Third, with regard to the arguments on utilities of a genus does not explain or discriminate a species, Examiner notes that Saulle et al. does teach that the primers identify only one single specific species, ruminants (deer) and primers derived from said known sequence that identifies said species would obviously result in a number of primers that would identify only said species and does not have the ability to identify a non-ruminant species as asserted by the Applicants. In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), regarding structural or functional homologs, the court stated "Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide

the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." (Since the claimed primers simply represent structural homologs of the primers of Lowe et al. derived from the prior art sequence of Saulle, which suggests that the prior art primers from ATPase8 are useful only in the identification of a specific species (deer or ruminant animal species), and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, and said genus of primers all belong to identify said specific species As stated in MPEP 2144.08, which notes "obviousness does not require absolute predictability, only a reasonable expectation of success; i.e. , a reasonable expectation of obtaining similar properties. See , e.g. , In re O'Farrell , 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)." In this factual case, there is express suggestion in the prior art that the primers should be used in differential display by Fislage, and Liang, the original source of the method of differential display, expressly teaches the use of primer combinations. The is sufficient for a reasonable expectation of success. The MPEP cites In re O'Farrell, which notes regarding "obvious to try" at page 1682, that, In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. E.g. , In re Geiger , 815 F.2d at 688, 2 USPQ2d at 1278; Novo Industri A/S v. Travenol Laboratories, Inc. , 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); In re Yates , 663 F.2d 1054, 1057,



211 USPQ 1149, 1151 (CCPA 1981); In re Antonie , 559 F.2d at 621, 195 USPQ at 8-9. In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. In re Dow Chemical Co ., 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); Hybritech, Inc. v. Monoclonal Antibodies, Inc ., 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1 986), cert. denied , 107 S.Ct. 1606 (1987); In re Tomlinson ; 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966). As discussed in the previous office action, there is express suggestion in the prior art that the primers are used to identify one specific species, that is to identify ruminants and designing primers from said known target sequence as taught by Lowe et al. would result only in primers that would identify said single specific species. This is sufficient for a reasonable expectation of success that the combination would result in primers that would only have utility in distinguishing said specific species since the Saulle et al. reference explicitly taught that the primers derived from said ATPase8 gene would identify only ruminant species.

With regard to the arguments drawn to no motivation or suggestion to combine the references, examiner notes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, specific motivation is provided in the rejection, which states that the ordinary artisan would have been motivated to generate a number of said primers and primer pairs for detection of

ruminant-specific DNA using said known sequence that identifies a specific species, such primers and primer pairs are considered functionally equivalent to the claimed primers and primer pairs. Accordingly the rejection is maintained and rewritten as above.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

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